RESEARCH ARTICLE

DO PATIENTS WITH CHRONIC LOW BACK PAIN EXPERIENCE PAIN REDUCTION AND FUNCTIONAL IMPROVEMENT AFTER TREATMENT AT A MULTIDISCIPLINARY OUTPATIENT CLINIC?

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ABSTRACT

Background: Low back pain is the most common affliction of the musculoskeletal system. Patients with chronic low back pain cost the society great expenses in treatments and other social benefits; however, the effects of interventions are discussed. The purpose of this study was to determine whether patients with chronic low back pain experience pain reduction and functional improvement after treatment at a multidisciplinary outpatient clinic.

Methods: A prospective study design was used, including 446 patients who participated in follow-up questionnaires with data collection at 6 and 12 months after treatment. The primary outcome was alterations in pain and function.

Result: By 12 months after treatment, 71.3 % of the included patients had completed the follow-up questionnaires. Based on these questionnaires, we identified statistically significant changes from baseline at all end points, with clinically significant changes in approximately half of the participants (p = 0.000).

Conclusion: Treatment of chronic low back pain at a multidisciplinary outpatient clinic resulted in clinically significant pain reduction and functional improvement within 12 months for approximately half of affected patients.

Keywords: prospective cohort study, chronic low back pain, pain reduction, functional improvement, multidisciplinary outpatient clinic.

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INTRODUCTION

Afflictions of the musculoskeletal system are the most common reasons for work absence and for seeking health treatments in Norway [1]. Back pain is the most common musculoskeletal disorder [2,3], leading to 35 % of all work absences and 30 % of new disability pensions per year. The prevalence of back pain is highest among middle-aged people, especially in industrialized countries, and has been described as an increasing problem [4]. A recent study [5] found that, compared to controls, people with chronic low back pain (CLBP) have a much higher prevalence of co-morbidity, particularly depression, anxiety and sleep disorders. In a Norwegian study [6], only 1.6 % of patients reported isolated lumbar pain.

Low back pain (LBP) is the most common localization of back pain. Typically, three classifications exist for LBP: unspecific LBP, LBP with nerve root Affliction and LBP with a possible malignant underlying condition [7]. Unspecific LBP is by far the most common. persistent low back pain lasting for three months of more is categorized as CLBP, and ordinarily requores a treatment plan comprising both physical exercises and cognitive training [5,7,8]. A recent review [9] reported that most multidisciplinary treatment studies have shown only short-term effects for the treatment of CLBP.

Norwegian patients with CLBP are frequently admitted to back schools with quite heterogeneous content [10,11]. There is evidence that conservative treatment is effective for several subgroups, both for those presenting with unspecific LBP and for those with specific causes for the affliction [12-14]. Originally, back schools were introduced in Sweden to serve as an intervention for patients with CLBP [15]. Since its introduction, the back school concept has been widely used, with large variations in the content, intensity, and duration of treatments provided [16]. The effectiveness of back school-associated interventions has been debated. Two review studies have reported that past research in this field has been of low methodological quality [8,15]. Several studies have compared interventions offered at back schools with other types of interventions [8,10,11,15,17-20], and most found that back school interventions provide short-term improvement. Other studies have found significant long-term differences after treatments containing both physical exercise and cognitive components [11,18,21].

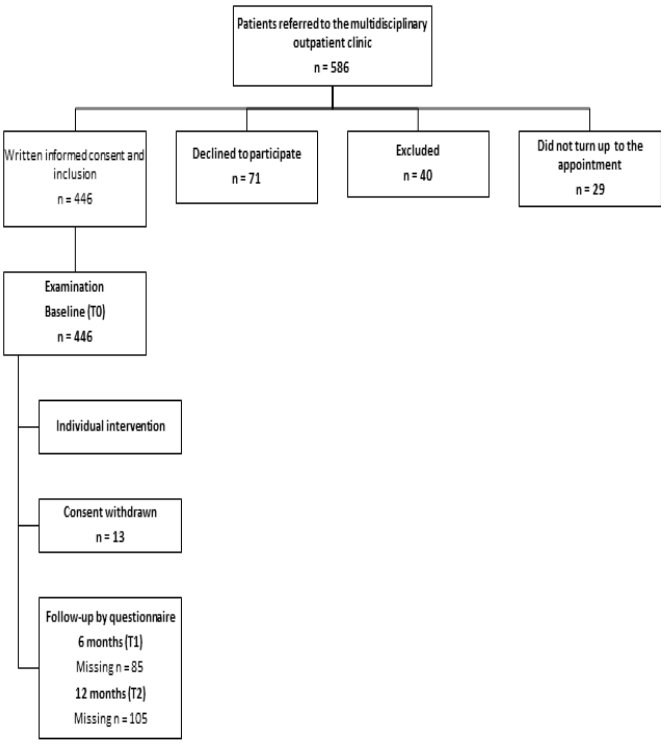
The aim of the current study was to determine the extent to which patients benefit from the treatments offered at our outpatient clinic. In particular, we sought to determine whether our patients experience long-term pain reduction and improvement of functional status. To accomplish this, we followed up with a group of patients for 12 months, with the specific goal of answering the following question: *Can a multidisciplinary outpatient back school reduce low back pain and improve functional status in a consecutively recruited patient cohort for at least 12 months?*

MATERIALS AND METHODS

Study population

Patients with CLBP were referred from general practitioners or hospitals in Møre and Romsdal County, western Norway. Over the period spanning from March 2013 through September 2014, 586 patients were referred to our multidisciplinary clinic; of these, 548 patients attended their scheduled appointments, and 29 patients canceled. Forty of the patients were excluded based on our exclusion criteria, and 71 of the patients chose not to participate in the study. In total, 446 patients provided written informed consent and were included for further intervention. Thirteen patients withdrew their consent during the intervention period.

Figure 1: Flow chart of the study – design, procedures and data collection



We included patients of both genders who were above the age of 18 and presented with CLBP. The questionnaires used for this study were complex and linguistically nuanced; therefore, we excluded patients with inadequate knowledge of the written Norwegian language. The Ethics Committee for Medical Research in the Southeastern Health Region has presented this study. We did not need approval as all the patients got the best appropriate care.

Intervention

All patients completed a baseline questionnaire before the first examination. Each patient underwent an individualized, partly standardized examination by an experienced physiotherapist. The patients were then invited to participate if they met the inclusion criteria. The physiotherapist filled in an individual record containing relevant clinical information.

The patients participated in one or several of the available treatment programs Table 1. The content, type, and duration of therapy were individualized and recorded by the physiotherapist. Six and twelve months after the baseline visit, the patients were followed up with questionnaires,

regardless of whether the patients were still receiving treatment. We used one phone call reminder after ten days if we missed a response to the follow-up questionnaires. After completing the twelve-month follow-up, participation in the study was complete.

At the baseline visit, the physiotherapist diagnosed each participant based on clinical and radiological findings. The patient was then categorized into a predefined category (skeletal; ICD-10 M40-49, intervertebral disc; ICD-10 M51 or muscle/soft tissue affliction; ICD-10 M54) based on the International Statistical Classification of Diseases and Related Health Problems.

Table 1: The Treatment Programs

Intervention	Description	Duration
Back School	An outpatient course. Lessons and group discussions (L), indoor training (T), hydrotherapy (H) and outdoor walks (O)	10 days
Follow-up day after the back school	Lessons and group discussion (L), indoor training (T) and hydrotherapy (H)	1 day
Indoor training	Cardiac training, weight training, stretching exercises and relaxation	90 min
Hydrotherapy	Training in a warmed-up pool. Weight training, stretching exercises and relaxation	60 min
Individual treatment	One-to-one treatment (I) with the physiotherapist	30-60 min
Cognitive therapy	One-to-one treatment (CT) with the physiotherapist	30-60 min
Control appointments	All patients had regular appointments (C) with the physiotherapist during treatment	30-60 min

Footnote Table 1:

- Lessons (L) were conducted by a physiotherapist, a clinical nutritionist, and a neurologist.
- Indoor training (T): Ongoing 3 times a week and were instructed by a physiotherapist. The group consisted of approximately 12 patients, were conducted in the gymnastics hall and used body-weight as weight load.
- Individual treatment (I): Including learning of training programs, soft tissue treatment, vocational guidance or another follow-up.
- Cognitive therapy (CT): Included identification and alteration of negative thoughts.
- Control appointments: One-to-one sessions with the physiotherapist, containing follow-up and re-examination.

Outcome measures

The primary outcome measures included alterations in pain and functional status. The secondary outcomes included changes in thoughts and beliefs concerning back pain and determination of whether such changes were related to diagnostic classification. Each patient answered an identical questionnaire at baseline (T0), six months (T1) and 12 months (T2).

Pain

Pain was measured according to the 11-point Pain Intensity-Numerical Rating Scale (PI-NRS) [22]. This outcome measure has previously been validated in a Norwegian population with CLBP [23]. A reduction of ≥ 2 points or a 30 % improvement in PI-NRS score was considered a clinically significant change [22,24].

Function

Changes in disability and function were assessed using the Oswestry Disability Index (ODI) [25], a recommended measurement tool for people with CLBP [23] and a validated outcome measure for functional changes in people with back problems [25,26]. Furthermore, a Norwegian translation of the ODI is available [27]. A reliable change is ≥10 units, as lesser changes can result from coincidence or measuring errors [25]. The cut-off value for the ODI has been set to 12 [24,28].

Thoughts and beliefs

The Fear-Avoidance Beliefs Questionnaire (FABQ) was previously developed to assess thought patterns regarding back pain during physical activity and work [29]. A high score on the FABQ indicates that the individual fears movement [30]. The FABQ has been used to measure fear avoidance in several studies [18,31-33].

Information on employment status was obtained from each patient at T0, T1, and T2. We also sought to determine whether changes in pain, functional status, and fear-avoidance beliefs were related to different Diagnostic categories.

Statistical analyses

The input collected by questionnaires was continuously registered in a password-protected web-database. The database was developed in cooperation with the Unit for Applied Clinical Research at Norwegian University of Science and Technology (NTNU). Differences between the entire follow-up group and those lost from baseline were tested with Pearson's Chi-Square test or Fischer's Exact test for categorical variables and Mann-Whitney U-test for continuous variables.

Changes from baseline to 12 months' follow-up on primary and secondary outcomes were tested using ANOVA for Repeated Measurements.

RESULTS

The current prospective cohort study included 446 patients, comprising 76 % of all referrals to our multidisciplinary outpatient clinic over a 19-month period spanning 2013 and 2014. By 12 months after study initiation, 71.3 % of the included patients had completed follow-up questionnaires. A complete follow-up was obtained for patients who underwent a higher number of consultations during the intervention period. When comparing the recorded baseline data to data comprising all patients (including dropouts) versus data including only patients who completed the study, no significant differences were recorded except for age and marital status. There were a higher number of dropouts in the younger age group, which offers a probable explanation for the observed difference in marital status. Descriptive results regarding the participants are shown in Table 2.

In total, 54 % of the included participants were women, and the mean age was 44 years. Pain duration was more than two years in 40 % of the participants, and 76 % of the

participants had already tried treatments for LBP before referral to our clinic. The average pain levels at baseline were 4.6 during rest and 5.8 while engaged in an activity. The patients were categorized based on their clinical diagnoses at baseline. Of the 428 participants, muscle and soft tissue afflictions were present in 71.5 % of the patients. Just over 19 % of the patients had intervertebral disc afflictions, and 9.1 % had skeletal structure disorders.

Primary outcomes

Table 2: Demographic and clinical baseline characteristics

	Baseline for the entire material (N = 428)	Complete follow-up group (N = 305)	Missing (N = 123)	P value
Age (mean, SD, range)[i]	44 (12.6) 18 - 85	46.2 (12.6) 18 – 86	38.5 (11) 18 – 67	0.000
Sex, women[i]	231 (54%)	171 (56.1%)	60 (48.8%)	0.171
Married/ live with significant other[i]	304 (71 %)	224 (73.4 %)	80 (65 %)	0.040
Educational level	Completed upper secondary school: 294 (68.8 %) Completed higher education: 134 (31.2 %)	Completed upper secondary school: 208 (68.2 %) Completed higher education: 97 (31.8 %)	Completed upper secondary school: 86 (69.9 %) Completed higher education: 37 (30.1)	0.579
Occupational status**	Working, homemaker or student: 343 (55.7 %) Retired: 17 (2.8%) On sick leave: 168 (27.3 %) Unemployed, on assessment allowance pension (AAP) or receiving disability benefits: 87 (14.2 %)	Working, homemaker or student: 242 (55.4 %) Retired: 15 (3.4 %) On sick leave: 121 (27.7 %) Unemployed, on assessment allowance pension (AAP) or receiving disability benefits: 59 (13.5 %)	Working, homemaker or student: 101 (40.1 %) Retired: 2 (0.8 %) On sick leave: 121 (48.0 %) Unemployed, on assessment allowance pension (AAP) or receiving disability benefits: 28 (11.1 %)	NA
Duration of pain*	No pain: 13 (3 %) Less than 3 months: 48 (11.2 %) 3-12 months: 154 (36 %) 1-2 years: 42 (9.8 %) > 2 years: 171 (40 %)	No pain: 12 (3.9%) Less than 3 months: 34 (11.1%) 3-12 months: 109 (35.7%) 1-2 years: 30 (9.8%) > 2 years: 120 (39.3%)	No pain: 1 (0.8%) Less than 3 months: 14 (11.4%) 3-12 months: 45 (36.6%) 1-2 years: 12 (9.8%) >2 years: 51 (41.5%)	0.514*
Pain (mean, SD)[i] 1) In rest 2) In activity	 1) 4.8 (2.3) 2) 5.8 (2.4)	 1) 4.6 (2.3) 2) 5.7 (2.4)	 1) 5.2 (2.3) 2) 6.0 (2.3)	 1)0.035 2) 0.252
ODI (mean, SD)[i]	27.6 (13.1)	27.6 (12.9)	27.6 (13.8)	0.998
Comorbidity: No[i] Reported by GP	356 (83.2 %)	254 (83.3%)	102 (82.9%)	0.930
Previous treatment: No[i]	104 (24.3 %)	73 (23.9 %)	31 (25.2 %)	0.782
Diagnose categories:[i] 1) Skeletal 2) intervertebral disc 3) Soft tissue	 1) 39 (9.1 %) 2) 83 (19.4 %) 3) 306 (71.5 %)	 1) 25 (8.2 %) 2) 65 (21.3 %) 3) 215 (70.5 %)	 1) 14 (11.4 %) 2) 18 (14.6 %) 3) 91 (74.0 %)	0.208

[i] Pearson Chi-square

* Mann Whitney U-Test

**Fisher's exact test

Our main outcomes were changes in pain and functional status after receiving treatment at our multidisciplinary outpatient clinic. A summary of the primary and secondary outcomes is shown in Table 3.

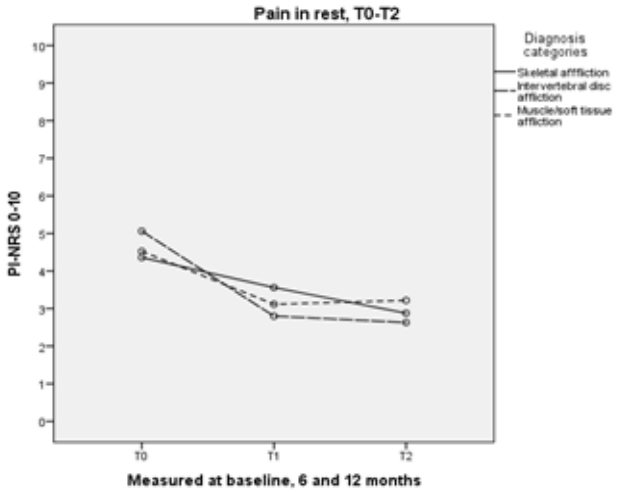
Table 3: Results primary and secondary outcomes

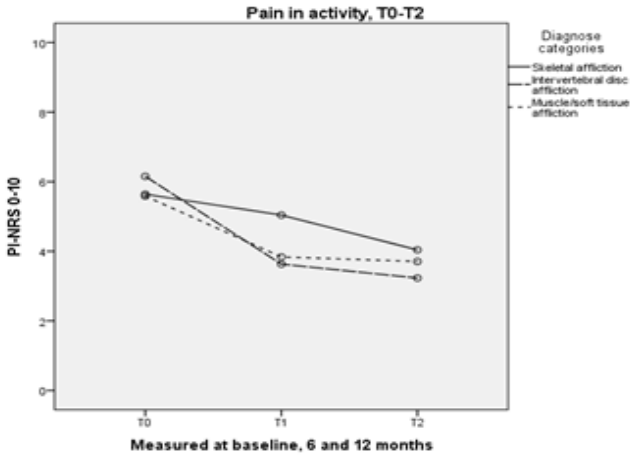
	Baseline	T1	T2	Mean (SD) change (T0-T2)	Clinical significant change	P value*
PI-NRS in rest N = 305 Mean (SD) CI:	4.6 (2.3) 4.4 - 4.9	3.1 (2.2) 2.8 – 3.3	3.1 (2.2) 28 – 3.3	-1.56 -1.85 - -1.27	N= 151 (49.5 %)	0.000
PI-NRS in activity N = 305 Mean (SD) CI	5.7 (2.4) 5.44-5.98	3.9 (2.5) 3.60 – 4.18	3.6 (2.6) 3.34 – 3.92	-2.1 - 1.8 – -2.4	N = 165 (54.1%)	0.000
ODI N = 304 Mean (SD) CI	27.6 (12.8) 26.16–29.06	19.9 (13.7) 18.35 – 21.44	19.7 (14.4) 18.06 – 21.31	-7.93 (14.0) - 9.5 - -6.35	N = 131 (43.1 %)	0.000
FABQ PA N = 300 Mean (SD) CI Cut-off ≥ 16	11.58 (5.44) 10.96 – 12.20 166 (24.9 %)	7.85 (6.12) 7.16 – 8.55 47 (13.7 %)	7.40 (6.14) 6.70 – 8.09 42 (13.1 %)	-4.18 (6.9) -5.97 - -3.40		0.000
FABQ work N = 260 Mean (SD) CI Cut-off ≥25	20.72 (11.04) 19.37 – 22.07 158 (39.5 %)	16.33 (11.52) 14.92 – 17.73 83 (26.1 %)	16.58 (12.08) 15.10 – 18.06 74 (24.9 %)	- 4.15 (9.7) -5.33 – -2.98		0.000

*All measures were analyzed using T-test for Repeated Values

Overall, we found a mean change of 1.56 units in pain during rest one year after baseline, which was significant, and a mean change of 2.1 units in pain during activity according to PI-NRS score. With respect to PI-NRS score, changes of 2 units are considered clinically significant. One year after baseline, 49.5 % of the participants in this study had a change 2 in PI-NRS^{rest}, and 54.1 % had a change in 2 in PI-NRS^{activity}. By stratifying the participants into different diagnostic categories, as shown in Figure 2a and 2b, we found that individuals with intervertebral disc afflictions showed the largest improvement, with a change of 2.6 units in pain during rest and of 3.2 units during activity.

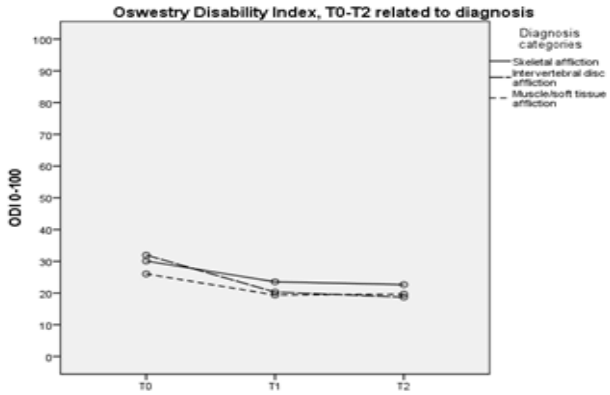
Figure 2A AND 2B: Changes in pain by the diagnostic categories using the pain intensity – numerical rating scale (pi-nrs) in activity and rest





We measured functional changes with the ODI and found a mean reduction of 7.9 units in the participants that completed the study. A clinically relevant change was considered to be 10 units; hence, 43.1 % of the participants showed clinically significant functional improvement 12 months after initiating treatment. For a healthy population, the cut-off for ODI score change is typically set at 12 units. In the current study, 12.5 % of the participants had ODI scores below 12 at baseline, 33.8 % had scores less than 12 after six months, and 37 % (113 participants) were below the cut-off after 12 months. When stratifying the participants according to diagnostic categories, the participants with intervertebral disc afflictions showed the lowest functional levels at baseline and the largest improvements after one year (Figure 3).

Figure 3: changes in function by diagnostic categories, using the Oswestry Disability Index (ODI)



Our secondary outcome included changes in thoughts and beliefs concerning pain experienced during activity and work, as measured by FABQ score. By 12 months after initiating treatment, all of the participants showed significant improvements in this regard, with mean changes of -4.8 for the FABQ physical activity score and of -4.15 for the FABQ work score. There is currently no consensus on what constitutes a relevant cut-off score for this measurement tool, but we chose a cut-off of ≥16 in the FABQ physical activity questionnaire and ≥ 25 for the FABQ work. There were no significant differences in FABQ score between the different diagnostic groups.

Another observation made at follow-up was a reduction in sick leave. At baseline, 40 % of the patients were on sick leave. By six months after initiating treatment, 17 % were

on sick leave, and only 10 % reported work absence after 12 months of treatment. This change was significant.

DISCUSSION

This study was designed to examine the effects of a treatment intervention for CLBP that was organized and performed at our multidisciplinary outpatient clinic. To accomplish this, we measured pain reduction and functional improvement in participants over a 12-month course of follow-up. We found statistically significant changes from baseline at all end points and clinically significant changes in approximately half of the participants by 12 months after treatment initiation. We also observed clinically significant pain reduction in 49.5 % and 54 % of the participants, as measured by PI-NRS^{rest} and PI-NRS^{activity} scores, respectively. Finally, 43 % of the patients experienced functional improvements of at least ten units as measured by the ODI.

Numerous pain outcome measures exist [34]. In the current study, we chose to follow up the included participants using the PI-NRS, which has been previously recommended for use by Norwegian authors [23] for CLBP. Using this measure, we found that approximately half of our population experienced clinically significant improvement. This is a result that is concordant with a previous conservative intervention study by Marchand and colleagues from 2015 [35]. One reason for the higher PI-NRS^{activity} scores may be that the intervention focused mostly on managing pain experienced during regular activity and training, and the specificity of this emphasis may have influenced the tolerance and experience of pain.

When examining different diagnostic categories, the participants with intervertebral disc afflictions showed the highest levels of improvement in the majority of the measured variables (Figure 3). According to PI-NRS^{rest} score, 63 % of the participants with an intervertebral disc disorder showed clinically significant improvements, and 61.5 % of this group also showed significantly improved PI-NRS^{activity} scores. These results are following previous studies by Iversen et al. from 2012 and Albert and colleagues from 2015, indicating that individuals with radiculopathies have a good prognosis with conservative treatment [12, 36]. The participants with skeletal system disorders showed the same improvement as the participants in the other two groups, but these improvements followed a unique course. As shown in Figure 2a, the participants with skeletal system disorders showed a more gradual course of improvement compared to the other groups that had a larger drop in improvement towards six months, after which their measurements plateaued.

According to a review article published in 2011 by Kamper et al. [34], recovery from LBP has been inconsistently measured. For example, the frequently used dichotomization between "recovered" and "not recovered" does not take into account the nuanced levels of recovery, whereas changes in percentages or points made using various measurement tools [9] can indicate when a patient has shown clinical improvement without complete recovery.

In the current study, we examined both dichotomized and continuous endpoints to obtain a comprehensive assessment of our study population. For example, several previous studies by van Hooff et al.; 2014, Iversen and colleagues; 2015 and Haugen et al. 2011 have used ODI score cut-off values of approximately 20 points when determining the effectiveness of a treatment [9,12,37]; however, the mean ODI score for a healthy population is 10 (SD 1-12) [24,25,28]. Therefore, we chose a cut-off value of 12 for ODI score when assessing functional impairment. This approach might have given us more limited results, although it probably more closely describes the functional impairment in the included patients about the general population. When applying a cut-off value of 12, we found that 12.5 % of our patients had a healthy functional status at baseline, 33.8 % had a functional status comparable to a healthy population after six months, and 37 % had a healthy functional status after 12 months. Another factor that might influence our results is that the ODI scores at baseline were low compared to other studies. Our mean ODI score was 27. Other studies report mean scores ranging from 41 to 43 [9,25]. Thus, a low initial score might affect the measurement of an individual's potential for disability improvement by more than ten units. Accordingly, we also wanted to assess functional improvement in a dichotomised manner.

Norwegian national guidelines from 2007 [7] estimate that approximately 75-80 % of the population have non-specific LBP, which is following our baseline data, wherein over 70 % of our participants were categorized as having non-specific muscular afflictions. Our target population was people with LBP lasting for more than three months, thus fulfilling the requirements for CLBP. The baseline characteristics of the participants showed that most had been experiencing pain for at least two years. The mean age of the participants was 44 years, and the cohort included a slightly higher percentage of women than men. These characteristics were in accordance with other studies [4,9,38,39], indicating that the population we studied is representative of a Norwegian population with CLBP.

People with CLBP are assumed to have a poor prognosis concerning return to work (RTW) [40]. However, in recent years, there has been a decline in work absence and disability benefits [3]. In a prospective study on long-term return to work after rehabilitation for CLBP [40], a worse prognosis for RTW was found if sick leave exceeded six months. Thus, we consider it encouraging that the percentage of participants on sick leave in our study decreased from 40 % at baseline to only 10 % after one year. As this was a tertiary outcome in our study, we only have information about sick leave at one defined point in time. Thus, we have no data to confirm that the reduced number of patients on sick leave was sustained. Additionally, we did not obtain information regarding the duration of sick leave before participation in our clinic.

One strength of the current study is the inclusion of patients from many age groups with a variety of afflictions and pain durations. This provided an excellent overview of the patient population in our area. We also applied a systematic, structured follow-up after participation in our multidisciplinary clinic, enabling us to review the effects of certain treatments at varying time points after the inter-

vention. To the best of our knowledge, this is the first cohort study that has categorized a population of individuals suffering from back pain according to diagnostic categories in the ICD-10 to determine whether end points differ in relation to diagnosis.

The dropout rate in our study was considered low. More than 70 % of the participants replied to the repeated questionnaires, thus providing information on a large representative group of people with CLBP. One limitation to the current study, however, is that the number of individuals who dropped out was somewhat skewed towards a younger population. As such, there was a possible loss of information from younger people [37]. Poulain and colleagues published in 2010 an article on predictive factors [40] and found that age is a predictive factor for a favorable prognosis for those younger than 35 years, an observation that could have affected our results.

This study was a single-center study, which makes the transferability of our results to the national and international level somewhat limited. However, there was a good correlation between our descriptive data and the data underpinning the Norwegian national guidelines [7] on gender, socioeconomic status, and frequency of mental distress. This similarity suggests that our findings can be valid for comparable populations. Despite the large population sample included and the 12-month follow-up period, this study was still somewhat limited by its relatively short duration. The study size, however, compares to other LBP populations [9,12,39]. It could be of interest to have an extended follow-up in the future to assess the status of LBP after a longer period of time. As LBP can be relapsing and complex, it is natural to assume that the treatment effects will change over time.

The heterogeneity in the current study encompassing different types of LBP, various treatment interventions and dissimilar treatment intensities and durations might impact how the results convey to other populations [34]. In the clinical setting, however, a certain degree of individual adaptation is necessary and recommended [13]. This is reflected in the diversity of treatment options included in the study.

CONCLUSION

In conclusion, treatment at a multidisciplinary outpatient clinic led to clinically significant pain reduction and functional improvement for approximately half of the included population 12 months after undergoing treatment for CLBP.

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